UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENT
UNITED STATES PATENT AND TRADEMARK OFFIC
WASHINGTON, D.C. 20231
www.uspto.go

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

MAR 14 2003

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,545,644 was filed on February 19, 2003, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, RELPAX®, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved.

Is the active ingredient of RELPAX® eletriptan (as suggested by the Approval letter dated December 26, 2002) or is it eletriptan hydrobromide (as stated in the "NMEs Approved in Calendar Year 2002" and the "Prescription and Over-the-Counter Drug Product List - 22nd Edition Cumulative Supplement Number 12: dated December 2002")?

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosures:
Approval letter (four pages)
NMEs Approved in Calendar Year 2002 (two pages)
(http://www.fda.gov/cder/rdmt/NMECY2002.HTM)
Prescription and Over-the-Counter Drug Product List - 22nd Edition Cumulative Supplement Number 12: dated December 2002, http://www.fda.gov/cder/rxotcdpl/pdpl_200212.htm (one page of the document)

cc: A. David Joran
Pfizer Inc.
Legal Division
150 East 42nd Street
New York, NY 10017-5755

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

NMEs Approved in Calendar Year 2002

NDA Number	Generic Name	Trade Name	Dosage Form	Applicant	*Classification	Approva Date
21-232	Nitisinone	Orfadin	Capsule	Swedish Orphan	1PV	01-18-200
21-286	Olmesartan Medoxomil	Benicar	Tablet	Sankyo	1S	04-25-200
21-344	Fulvestrant	Faslodex	Injection	AstraZeneca	1S	04-25-200
21-272	Treprostinil Sodium	Remodulin	Injection	United Therapeutics	1PV	05-21-200
21-266	Voriconazole	VFEND	Tablet	Pfizer	1S	05-24-200
21-191	Dimyristoylphosphatidylcholine/ Perflexane	Imagent Kit for the Preparation of Perflexane Lipid Microspheres	Injectable Suspension	Alliance Pharm	1S	05-31-02
21-196	Sodium Oxybate	Xyrem	Solution	Orphan Medical	1PV	07-17-02
21-200	Tegaserod Maleate	Zelnorm	Tablet	Novartis	1P	07-24-02
21-492	Oxaliplatin	Eloxatin	Injection	Sanofi	1P	08-09-02
21-449	Adefovir Dipivoxil	HEPSERA	Tablet	Gilead	1P	09-20-02
21-437	Eplerenone	Inspra	Tablet	GD Searle	1S	09-27-02
21-445	Ezetimibe	Zetia	Tablet	MSP Singapore	1S	10-25-02
21-436	Aripiprazole	Abilify	Tablet	Otsuka	1S	11-15-02
21-498	Nitazoxanide	Alinia	Suspension	Romark	1PV	11-22-02

21-411	Atomoxetine Hydrochloride	Strattera	Capsule	Lilly	1S	11-26-02
21-321	Icodextrin	Extraneal	Solution	Baxter Healthcare	1SV	12-20-02
21-016	Eletriptan Hydrobromide	Relpax	Tablet	Pfizer	1S	12-26-02

***Classification**
Chemical Type:
1 - New molecular entity

Therapeutic Potentials:
P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.
S - Standard Review - The drug appears to have therapeutic qualities similar to those of one or more already marketed drugs.
V - Orphan Drug

Top of Page

FDA/Center for Drug Evaluation and Research
Page Last Updated: January 08, 2003
Originator: CDER/OND
HTML by SFD

			DOXYCYCLINE				
>A>			PAR PHARM	EQ 75MG BASE	N65070	003	DEC 30, 2002
			EDETATE DISODIUM				
			INJECTABLE; INJECTION				
			EDETATE DISODIUM				
>A>	AP		BIONICHE (CANADA)	150MG/ML	N40437	001	JUL 09, 2002
>D>	AP		PHARMAFORCE	150MG/ML	N40437	001	JUL 09, 2002
>A>			ELETRIPTAN HYDROBROMIDE				
>A>			TABLET; ORAL				
>A>			RELPAX				
>A>			PFIZER	EQ 20MG BASE	N21016	001	DEC 26, 2002
>A>		+	PFIZER IRELAND	EQ 40MG BASE	N21016	002	DEC 26, 2002
			ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE				
			INJECTABLE; INJECTION				
			DEPO-TESTADIOL				
>D>	AO	+	PHARMACIA AND UPJOHN	2MG/ML;50MG/ML	N17968	001	
>A>		+		2MG/ML;50MG/ML	N17968	001	
>D>			TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE				
>D>	AO		STERIS	2MG/ML;50MG/ML	N85603	001	MAR 13, 1986
>A>		@		2MG/ML;50MG/ML	N85603	001	MAR 13, 1986
>D>			ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE				
>D>			INJECTABLE; INJECTION				
>D>			DITATE-DS				
>D>		+	SAVAGE LABS	8MG/ML;180MG/ML	N86423	001	
>A>		@		8MG/ML;180MG/ML	N86423	001	
>D>			TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE				
>D>		+	STERIS	4MG/ML;90MG/ML	N85865	001	
>A>		@		4MG/ML;90MG/ML	N85865	001	
			ETHINYL ESTRADIOL; NORGESTIMATE				
			TABLET; ORAL-28				
			ORTHO TRI-CYCLEN				
>D>		+	ORTHO MCNEIL PHARM	0.035MG,0.035MG,0.035MG;0.18MG,0.21 5MG,0.25MG	N19697	001	JUL 03, 1992
>A>	AB	+		0.035MG,0.035MG,0.035MG;0.18MG,0.21 5MG,0.25MG	N19697	001	JUL 03, 1992
			TRI-SPRINTEC				
>A>	AB		BARR	0.035MG;0.18MG	N75808	001	DEC 18, 2002
			ETODOLAC				
			TABLET; ORAL				
			ETODOLAC				
>A>	AB		APOTEX	400MG	N76004	001	DEC 03, 2002
>A>	AB			500MG	N76004	002	DEC 03, 2002
			GALLIUM NITRATE				
			INJECTABLE; INJECTION				
			GANITE				
>D>		@	GENTA	25MG/ML	N19961	002	JAN 17, 1991
>A>		+		25MG/ML	N19961	002	JAN 17, 1991
			GATIFLOXACIN				
			INJECTABLE; INJECTION				
			TEQUIN				
>A>		+	BRISTOL MYERS SQUIBB	EQ 2MG /ML(200MG/100ML)	N21062	001	DEC 17, 1999
>A>		+		EQ 2MG /ML(400MG/200ML)	N21062	002	DEC 17, 1999
>A>				EQ 10MG /ML(200MG)	N21062	003	DEC 17, 1999
>A>		+		EQ 10MG /ML(400MG)	N21062	004	DEC 17, 1999
>D>		+		EQ 2MG /ML(200MG/100ML)	N21062	001	DEC 17, 1999
>D>		+		EQ 2MG /ML(400MG/200ML)	N21062	002	DEC 17, 1999
			HYDROFLUMETHIAZIDE				
			TABLET; ORAL				
			SALURON				
>D>	AB	+	SHIRE LABS	50MG	N11949	001	
>A>	AB	+		50MG	N11949	001	
			HYDROFLUMETHIAZIDE; RESERPINE				
			TABLET; ORAL				
			SALUTENSIN				
>D>		+	SHIRE LABS	50MG;0.125MG	N12359	003	
>A>		+		50MG;0.125MG	N12359	003	
			SALUTENSIN-DEMI				
>D>		@	SHIRE LABS	25MG;0.125MG	N12359	004	
>A>		@		25MG;0.125MG	N12359	004	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-016

Pfizer Inc.
Attention: Nancy Martin
50 Pequot Avenue
New London, CT 06320

Dear Ms. Martin:

Please refer to your new drug application (NDA) dated October 27, 1998, received October 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relpax (eletriptan) 20 mg, 40 mg, and 80 mg tablets.

Reference is also made to our December 1, 2000 approvable letter.

We acknowledge receipt of your submissions dated the following: June 27, 2002, September 20 and 27, 2002, October 29 and 30, 2002, November 7, 20, and 27, 2002 and December 9, 17, 23 and 26, 2002.

The June 27, 2002 submission constituted a complete response to our December 1, 2000 action letter.

This new drug application provides for the use of Relpax (eletriptan) tablets for the acute treatment of migraine.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to, except for including the revisions listed, the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-016.**" Approval of this submission by FDA is not required before the labeling is used.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will

work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lana Chen, Regulatory Project Manager, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple
12/26/02 04:53:01 PM